

EXHIBIT 1

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<p>1 THE WITNESS: So statistical 2 power depends on the expected degree of 3 difference between two groups and the 4 expected variability, and since those 5 things aren't known, you have to first 6 start by interrogating the data you have 7 and then see if that can predict for you 8 what kind of power that you need.</p> <p>9 So when you're saying it wasn't 10 powered, nobody has any idea what the 11 expected frequency of this condition is. 12 So there would be no way to a priori 13 power the study.</p> <p>14 BY MR. SLATER:</p> <p>15 Q. Do you know what Daiichi's 16 position is on whether or not this ROADMAP study 17 is adequately powered to answer the question of 18 whether or not olmesartan causes gastrointestinal 19 side effects?</p> <p>20 A. I do not.</p> <p>21 Q. If the study is not adequately 22 powered to answer that question, it would be 23 unscientific to rely on the study data to answer 24 the question; right?</p>	<p>1 THE WITNESS: Well, I think that 2 this is a useful document here in that it 3 gives us some sense of what the expected 4 event rates are, and now we have an idea. 5 But unfortunately for your case, there's 6 no difference between the placebo and the 7 olmesartan.</p> <p>8 So, you know, the onus is not to 9 prove that there's not an association.</p> <p>10 BY MR. SLATER:</p> <p>11 Q. Move to strike.</p> <p>12 Do I understand you correctly to 13 be saying the usefulness of the ROADMAP study is 14 it shows that, to the extent that 15 olmesartan-associated enteropathy exists, it's 16 rare or uncommon? Is that -- is that basically 17 what you're saying?</p> <p>18 MR. CHRISTIAN: Objection. Form.</p> <p>19 THE WITNESS: No. I'm saying 20 that what the ROADMAP study would argue 21 is that it doesn't exist.</p> <p>22 BY MR. SLATER:</p> <p>23 Q. Well, you can't get that 24 information from the ROADMAP study if it's</p>
<p>1 Page 231</p> <p>1 MR. CHRISTIAN: Objection. Form.</p> <p>2 THE WITNESS: That's a verbatim 3 question you just asked me, and I just 4 said to -- I can't determine whether it's 5 properly powered because we don't know 6 what the expected frequency in the 7 population of this is.</p> <p>8 You would have to know that in 9 order to make an a priori estimation of 10 what power should be.</p> <p>11 BY MR. SLATER:</p> <p>12 Q. Doctor, I'm not asking you if 13 it's adequately powered or not. We already know 14 you can't tell me that.</p> <p>15 My question is: Assuming it is 16 not adequately powered -- I'm going to rephrase.</p> <p>17 Assuming the ROADMAP study is not 18 adequately powered to give data that would be 19 useful regarding the frequency of 20 gastrointestinal side effects due to olmesartan, 21 you would not want to rely on it and it would be 22 unscientific to do so to answer the question of 23 causation; correct?</p> <p>24 MR. CHRISTIAN: Objection. Form.</p>	<p>1 Page 233</p> <p>1 underpowered to answer that question; right?</p> <p>2 MR. CHRISTIAN: Objection. Form.</p> <p>3 THE WITNESS: So what evidence do 4 you have that it's properly powered or 5 underpowered?</p> <p>6 BY MR. SLATER:</p> <p>7 Q. Hey, Doctor, you don't have an 8 opinion whether it's powered adequately or not; 9 right?</p> <p>10 A. That's true. All I can say is 11 it's an observation that might now provide 12 guidelines to now do a power analysis for the 13 next study.</p> <p>14 Q. Move to strike after "that's 15 true."</p> <p>16 You've already established nobody 17 would ever do such a study to -- to look at 18 gastrointestinal side effects because you already 19 told us it would take too many people and take 20 too long. Didn't you tell me that earlier?</p> <p>21 MR. CHRISTIAN: Objection. Form.</p> <p>22 THE WITNESS: Well, I think that 23 if that was the only purpose of the 24 study, that might be true, but I do</p>

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<p>1 realize now that there could be 2 opportunities if there were other studies 3 being done with olmesartan to look at 4 similar phenomenon as what was done in 5 the ROADMAP.</p> <p>6 Now with this in mind, I think 7 there could be a subcomponent of the 8 study where they could monitor the GI 9 side effects and potentially construct a 10 power analysis based on these data here.</p> <p>11 BY MR. SLATER:</p> <p>12 Q. You haven't done that analysis or 13 constructed any such study; right?</p> <p>14 A. No.</p> <p>15 Q. And it's speculation as you sit 16 here now that you're talking about. You're 17 speculating that something like that could be 18 done; right?</p> <p>19 A. I suppose, but it would be -- it 20 would be an attractive idea to get more insight 21 into this situation.</p> <p>22 MR. CHRISTIAN: Could we take a 23 quick bathroom break, Adam?</p> <p>24 MR. SLATER: Just one more</p>	<p>1 A. Can you tell me where that was? 2 Q. Sure. Right-hand column first 3 page, last paragraph. 4 "This finding might be because 5 sprue-like enteropathy is a rare event." 6 A. Right. Yeah, I see they say 7 that.</p> <p>8 MR. SLATER: All right. You want 9 to take a break?</p> <p>10 MR. CHRISTIAN: Yeah.</p> <p>11 THE VIDEOGRAPHER: Time now is 12 2:20. We are going off the record. This 13 is the end of Disk No. 3. 14 (A brief recess was taken.) 15 (Document marked for 16 identification purposes as Gutman 17 Exhibit 14.)</p> <p>18 THE VIDEOGRAPHER: The time now 19 is 4:40 -- excuse me -- 2:41. We're back 20 on the record. This is the beginning of 21 Disk No. 4.</p> <p>22 BY MR. SLATER:</p> <p>23 Q. Doctor, I have given you Exhibit 24 14, which is an article from Marthey et al.</p>
<p>1 question.</p> <p>2 BY MR. SLATER:</p> <p>3 Q. Doctor, I think you looked at the 4 letter to the editor by Menne and Haller while 5 you were trying to answer my question before?</p> <p>6 A. Yes.</p> <p>7 Q. Correct?</p> <p>8 A. Yeah.</p> <p>9 Q. Despite everything they said in 10 their letter, they said they can't rule out the 11 possibility of an association basically; right?</p> <p>12 A. (Reviewing document).</p> <p>13 They say they can't rule out that 14 this could be a very rare situation where it 15 could play a role, but their data do not identify 16 a link. That's what their conclusion is.</p> <p>17 Q. And they actually said just above 18 that that they didn't observe an intestinal 19 effect of olmesartan, but they said this finding 20 might be because sprue-like enteropathy is a rare 21 event; right?</p> <p>22 They actually acknowledge the 23 possibility that the study was underpowered to 24 show this; right?</p>	<p>1 "Olmesartan-associated enteropathy: result of a 2 national survey." 3 Are you familiar with that study? 4 A. Yes. 5 Q. Now, in this study, they point 6 out in part that when the patients were diagnosed 7 when they were actually under treatment, 8 olmesartan was not known as a potential cause of 9 enteropathy. Therefore, most patients were 10 treated as if they had an autoimmune enteropathy; 11 correct? 12 A. You'll have to point -- it's -- I 13 don't remember that exactly. Can you point out 14 where they say that? 15 Q. On page 1105 under Outcome First 16 paragraph. 17 A. Okay. 18 Q. So these doctors who were 19 treating these patients didn't have the benefit 20 of knowing that olmesartan was one of the 21 potential causes for what they were seeing; 22 correct? 23 A. Correct. 24 Q. Now, if you look at page 1106,</p>

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<p>1 there were patients who were stopped on 2 olmesartan and it says 9 out of 10 had clinical 3 remission. That's in the first carryover 4 paragraph by the left column.</p> <p>5 A. Right.</p> <p>6 Q. When olmesartan was reintroduced, 7 all had clinical relapses; correct?</p> <p>8 A. Yeah. Yes. They said that it 9 was reintroduced to 9, yes.</p> <p>10 Q. That fact that 9 out of 9 had 11 positive rechallenge -- rechallenges is evidence 12 supporting a finding of causality; correct?</p> <p>13 A. Well, as we've said before, this 14 was not any sort of controlled protocol. It's 15 just a retrospective description of a story.</p> <p>16 Q. Just out of curiosity, you're 17 sure there's no protocol for this study?</p> <p>18 A. Well, the methods just says: 19 "We contacted by e-mail 20 investigators to report their observations."</p> <p>21 So I'm not seeing anything here 22 about a unified protocol.</p> <p>23 Q. Okay. On page 1107 is the 24 discussion and they say in the first paragraph in</p>	<p>1 completely. I just say it's -- it's not the 2 higher level evidence.</p> <p>3 Q. You're not opining that these 9 4 patients didn't get better -- well, rephrase.</p> <p>5 Let me ask it differently.</p> <p>6 Is it your opinion that these 9 7 patients who are described here didn't really get 8 better when they got off the drug and didn't 9 really get sick again when they went back on 10 olmesartan?</p> <p>11 A. I can't really say for sure 12 because it's not the same thing. It's as a 13 controlled study. In other words, they just 14 accepted information from various GI docs in the 15 country. So it's not the same thing as a 16 well-defined follow-up.</p> <p>17 Q. Who would have a motivation to do 18 the sort of controlled study that you're 19 suggesting would need to be done in order to 20 prospectively evaluate olmesartan-associated 21 enteropathy? Who would actually have an 22 incentive to do that study and to spend that 23 money?</p> <p>24 MR. CHRISTIAN: Objection. Form.</p>
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<p>1 part: 2 "Olmesartan is likely to be 3 causal as interruptions were followed by clinical 4 remissions and reintroductions were followed by 5 relapses."</p> <p>6 Do you see that statement?</p> <p>7 A. Yes.</p> <p>8 Q. From a clinical perspective, 9 that's a reasonable medical judgment; correct?</p> <p>10 MR. CHRISTIAN: Objection. Form.</p> <p>11 THE WITNESS: You could argue 12 that in these 9 patients that there was 13 some suggestion that they had a reaction 14 to olmesartan that was specific to them, 15 and when they were restarted, there was a 16 relapse. That's what they've stated 17 here, but, again, it's not really under 18 any specific protocol.</p> <p>19 BY MR. SLATER:</p> <p>20 Q. You discount this data because 21 there wasn't a protocol and because it wasn't a 22 controlled study; is that correct?</p> <p>23 A. Well, in my report, I called it 24 "Level IV evidence." So I don't throw it out</p>	<p>1 THE WITNESS: Right. I don't 2 disagree with you.</p> <p>3 But what I'm saying is that, as 4 we were just talking about in the ROADMAP 5 study, if you have a lot of patients that 6 you're tracking very carefully, like I 7 used the example of the Framingham Heart 8 Study or the Nurses Health Study, there's 9 much more opportunity to interrogate that 10 data in a systematic way rather than just 11 receiving cases that come into you via 12 community practice doctors.</p> <p>13 BY MR. SLATER:</p> <p>14 Q. Move to strike after the "right." 15 I think he said something to the effect of 16 "right, I don't -- I agree with you," or whatever 17 he said. I don't have the exact language but 18 moving to strike the last part of the answer.</p> <p>19 In terms of evaluating 20 olmesartan-associated enteropathy, sprue-like 21 enteropathy, whatever you want to call it, the 22 evidence of dechallenges and rechallenges has to 23 be looked at as an important component of the 24 analysis; correct?</p>

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<p>1 A. If they were properly done, but 2 we've been down this road before in this 3 deposition where I've said that I don't think 4 that these case reports constitute what I would 5 consider a proper challenge and rechallenge.</p> <p>6 Q. Are there any dechallenges or 7 rechallenges that you feel are of a sufficient 8 level of scientific evidence that you actually 9 think that they are of significance that you've 10 seen any article or study you've seen?</p> <p>11 A. Well, I'm thinking about things 12 like clinically. There are children that have 13 severe food allergies, and they see experts in 14 this. And then what happens is their life is 15 really turned upside down by the fear that 16 they're going to have anaphylactic shock if 17 they're in the room with somebody that's eating 18 peanuts or what have you, and there are 19 physicians that specialize in slowly and 20 meticulously re-challenging those children to 21 determine what foods they can be around and what 22 foods they can eat.</p> <p>23 That's just a clinical example of 24 how there are people with a lot of experience</p>	<p>1 Do I understand that? 2 MR. CHRISTIAN: Objection. Form. 3 THE WITNESS: You know, as I've 4 been trying to say here, I'm not taking 5 articles that people did their best to 6 write and just saying, I'm not going to 7 read it or I'm not going to consider it. 8 I'm saying that I'm going to 9 grade the level of evidence, and I just 10 feel like the level of evidence with 11 these challenge, rechallenge, as you call 12 it, is -- is low. 13 I'm not saying that I didn't read 14 it or consider it or that it can't be 15 considered at all or debated. I'm just 16 saying that it's -- the quality of the 17 evidence is low.</p> <p>18 BY MR. SLATER:</p> <p>19 Q. For the 9 patients who had 20 positive dechallenges and positive rechallenges, 21 as described in Marthey, olmesartan is the likely 22 cause of their clinical symptoms; correct?</p> <p>23 MR. CHRISTIAN: Objection. Form.</p> <p>24 BY MR. SLATER:</p>
<p>1 have study protocols for taking care of patients 2 with complex issues like that.</p> <p>3 Here we're just dealing with kind 4 of retrospective observations. These are 5 observational studies.</p> <p>6 Q. Okay. Move to strike.</p> <p>7 MR. CHRISTIAN: Did you finish 8 your answer?</p> <p>9 THE WITNESS: The last thing I 10 would say is just these are -- these are 11 observational studies.</p> <p>12 BY MR. SLATER:</p> <p>13 Q. Move to strike.</p> <p>14 My question is this: Are there 15 any documented dechallenges or rechallenges in 16 any of the articles that you're relying on for 17 your opinions that you consider to be valid 18 scientifically?</p> <p>19 A. I don't believe there are any, 20 no.</p> <p>21 Q. Since in forming your opinions 22 you have put aside all of the reports of 23 dechallenges and rechallenges as not being of any 24 real significance to you.</p>	<p>1 Q. Based on the information 2 available in this article?</p> <p>3 MR. CHRISTIAN: Same objection.</p> <p>4 THE WITNESS: I'm not sure I see 5 the word "rechallenge" or "dechallenge" 6 anywhere in this article, first of all.</p> <p>7 BY MR. SLATER:</p> <p>8 Q. No. I'm using the word 9 "rechallenge" and "dechallenge." But this talks 10 about the fact on page 1106: 11 "Olmesartan interruptions were 12 followed by clinical remissions in 9 of 10 cases. 13 Olmesartan reintroductions were followed by 14 clinical relapses in 9 of 9 cases." 15 So with regard to those 9 16 patients, the likely cause of their condition was 17 the olmesartan; correct?</p> <p>18 A. So --</p> <p>19 MR. CHRISTIAN: Objection. Form.</p> <p>20 THE WITNESS: -- one of the 21 confounding variables in the study that's 22 really problematic is a lot of these 23 patients were on steroids. 24 So I don't know how well it's</p>

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<p>1 delineated here whether the people -- so 2 let's imagine somebody gets better on 3 steroids, which controverts the Mayo 4 Clinic study, which we previously 5 discussed, where they indicated in that 6 study that 20 of the 22 patients had 7 failed to respond to steroids.</p> <p>8 Now we have this study where they 9 say that the majority of the patients 10 received steroids. So what could easily 11 have happened is that they might have 12 gone off -- they might have gotten better 13 on steroids.</p> <p>14 Steroids could be treating 15 something, autoimmune enteritis or some 16 form of inflammation caused by another 17 factor. They get better and then over 18 time maybe they were going to get worse 19 again anyway if they didn't get put back 20 on steroids.</p> <p>21 I really don't know. Like 22 Crohn's disease or anything like that, 23 and it just could be that they were 24 looking well and then they stopped the</p>	<p>1 just sort of another case series. 2 BY MR. SLATER:</p> <p>3 Q. From a clinical perspective with 4 the information that's here, it would be 5 reasonable clinical judgment by the doctors 6 treating those patients to determine that those 7 26 patients, the cause of their condition was 8 olmesartan.</p> <p>9 That would be a reasonable 10 clinical judgment in the course of treating that 11 patient; correct?</p> <p>12 A. I think that if they properly 13 ruled out much more common causes of the syndrome 14 of these types of conditions, then I think that 15 in the individual cases if a treating physician 16 feels that it's best to stop the olmesartan, I 17 don't have a problem with that.</p> <p>18 Q. The reason to stop the olmesartan 19 and actually not to put the patient back on it 20 because they already got better when they were 21 off it, the reason the doctor would be doing that 22 is because they believe the olmesartan was 23 causing the condition, so I don't want to put the 24 patient back on the drug.</p>
<p>1 steroids.</p> <p>2 We see all the time in patients 3 with -- with colitis that -- ulcerative 4 colitis or Crohn's that they get off the 5 steroids and then they get well and they 6 come off the steroids, they get sick 7 again. So there could be confounding 8 variables.</p> <p>9 BY MR. SLATER:</p> <p>10 Q. Well, looking at the summary on 11 the abstract on the start of the article. At the 12 bottom of the results, it says:</p> <p>13 "29 patients were in remission 14 since olmesartan interruption including 26 15 without immunosuppressants."</p> <p>16 You see what I just read?</p> <p>17 A. Yes.</p> <p>18 Q. For those 26 patients at least, 19 would you agree that the likely cause was the 20 olmesartan?</p> <p>21 MR. CHRISTIAN: Objection. Form.</p> <p>22 THE WITNESS: I mean, it's 23 possible. I don't know that I'm willing 24 to say likely because, again, this is</p>	<p>1 That would be a reasonable 2 clinical judgment; right?</p> <p>3 A. I would say right, except for the 4 fact that this is a very short paper, and I 5 really don't know what the treating physicians 6 were thinking. There's no -- there's no 7 information here about what the thought process 8 was of the treating physicians.</p> <p>9 Q. Move to strike from "except" 10 forward.</p> <p>11 I'm asking this: With regard to 12 the 26 patients who got off of olmesartan, got 13 better and they weren't taking 14 immunosuppressants, if those doctors said, I'm 15 not putting you back on olmesartan, I think 16 because of the dechallenge olmesartan was 17 probably causing your condition so you shouldn't 18 take it anymore, that would be a reasonable 19 clinical judgment; right?</p> <p>20 A. I would say for those individuals 21 that that would be a reasonable judgment.</p> <p>22 MR. SLATER: Laura, let's go to 23 document 4 and mark that as the next 24 exhibit.</p>

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1 THE REPORTER: Exhibit 15. 2 (Document marked for 3 identification purposes as Gutman 4 Exhibit 15.) 5 BY MR. SLATER: 6 Q. All right. Doctor, I've handed 7 you a case report and review of the literature. 8 The first author's last name is Kulai, K-u-l-a-i. 9 Do you see that? 10 A. Yes. 11 Q. And this -- this case report, if 12 you look on the case presentation -- I'm not 13 going to read the whole thing out loud, but if 14 you go through it and you just read along with 15 me, he had a 5-week history of non-bloody 16 diarrhea, vomiting, and 20-pound weight loss. 17 Do you see that right in the 18 beginning? 19 Do you see that, Doctor? 20 A. Oh, yeah. Sorry. Right at the 21 beginning. Okay. 22 Q. And those symptoms are consistent 23 with the syndrome of olmesartan-associated 24 enteropathy, sprue-like enteropathy described	1 go through his albumen, his electrolytes, etc. 2 Nonanion gap metabolic acidosis. 3 You see all that? 4 A. Yes. 5 Q. Negative for culturing, 6 parasites, C diff. All that was negative, and 7 then it shows that his testing for tTG antibodies 8 negative also; correct? 9 A. Right. 10 Q. Biopsy showed marked villous 11 blunting and near complete villous atrophy of the 12 small intestinal mucosa. Increase in 13 intraepithelial lymphocytes, neutrophils. It 14 talks about the crypts. 15 It gives what the histopathology 16 was; correct? 17 A. Right. 18 Q. It talks about the workup in the 19 hospital and the fact that he was negative for 20 syphilis, Lyme's disease, sarcoid, tuberculosis. 21 All that was negative? 22 A. Right. 23 Q. Right? 24 A. Yeah.
1 throughout the literature; correct? 2 A. They're consistent with, but they 3 could also be consistent with other things. 4 Q. Move to strike from "but" 5 forward. 6 There's then a history that's 7 given about an issue with his eye, and then they 8 go through that he had no fevers, no joint pain, 9 no skin changes, no recent travel, a past medical 10 history, including kidney stones, hypertension, 11 aortic valve replacement. 12 They go through his medications 13 including olmesartan, hydrochlorothiazide, which 14 is Benicar HCT. His other medications including 15 ASA, vitamin C, a multivitamin, cod liver, 16 acetaminophen. 17 Do you see all that? 18 A. Yes. 19 Q. Then they go through his blood 20 workup. He had an acute kidney injury, 21 presumably secondary to dehydration. 22 Do you see that? 23 A. Yes. 24 Q. He had normocytic anemia. They	1 Q. Then it shows that his diarrhea 2 resolved within two weeks of olmesartan 3 discontinuation, his anemia improved to baseline, 4 and he returned to his previous weight within 5 three months, and then 14 weeks later he had 6 complete resolution of the villous atrophy and 7 inflammatory changes. 8 Do you see all that? 9 A. Yes. 10 Q. If you look at that entire 11 picture as described, the likely cause of this 12 person's condition would be the olmesartan; 13 correct? 14 A. Well, on face value, you might 15 think that, but I do find this description of the 16 uveitis to be worrisome because uveitis is a 17 classic extraintestinal manifestation of Crohn's 18 disease. 19 Q. For what? 20 A. For Crohn's disease, which is 21 another disease. 22 Q. Would getting off of olmesartan 23 result in resolution of symptoms of Crohn's 24 disease if it was Crohn's disease?

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<p>1 A. No, I'm not saying that.</p> <p>2 I'm just saying that it's an odd</p> <p>3 scenario here that maybe this patient has some</p> <p>4 other sort of autoimmune disorder going on. I</p> <p>5 can't dispute the fact that as written here that</p> <p>6 the patient appears to have gotten better after</p> <p>7 the olmesartan, but uveitis is, you know, not</p> <p>8 something that's at all been associated with this</p> <p>9 syndrome and it seems to be concomitant with his</p> <p>10 situation. So would actually make me think about</p> <p>11 some sort of autoimmune situation.</p> <p>12 Q. If this patient had an unrelated</p> <p>13 autoimmune situation, you would not expect that</p> <p>14 getting off of olmesartan would resolve the</p> <p>15 histopathology and the symptoms as described</p> <p>16 here; correct?</p> <p>17 MR. CHRISTIAN: Objection. Form.</p> <p>18 THE WITNESS: I don't dispute</p> <p>19 that. I'm just saying that it could be a</p> <p>20 coincidence. I agree that it would be a</p> <p>21 bit of an unusual coincidence, but I</p> <p>22 don't believe that, you know, getting off</p> <p>23 the olmesartan should affect the eye, but</p> <p>24 somehow his eye improved.</p>	<p>1 BY MR. SLATER:</p> <p>2 Q. To a reasonable degree of medical</p> <p>3 certainty, the fact that the patient had full</p> <p>4 symptomatic and pathologic resolution after</p> <p>5 suspension of olmesartan within a 4-month period</p> <p>6 leads to the opinion that olmesartan was the</p> <p>7 likely cause to a reasonable degree of medical</p> <p>8 certainty; correct?</p> <p>9 MR. CHRISTIAN: Objection. Form.</p> <p>10 THE WITNESS: You know, I would</p> <p>11 love to see a higher powered view of that</p> <p>12 Figure 2. I'm not convinced that that</p> <p>13 biopsy is normalized. I mean, yeah, the</p> <p>14 villi are back, but it looks like to me</p> <p>15 like there's lamina propria expansion</p> <p>16 still. So it doesn't look completely</p> <p>17 normal to me.</p> <p>18 BY MR. SLATER:</p> <p>19 Q. Move to strike.</p> <p>20 Based upon the fact that there</p> <p>21 was full symptomatic and pathologic resolution</p> <p>22 after suspension of olmesartan, including the</p> <p>23 symptoms of non-bloody diarrhea, vomiting, and a</p> <p>24 20-pound weight loss, and histopathology as</p>
<p>1 I didn't -- I don't quite know</p> <p>2 whether they're trying to state that the</p> <p>3 olmesartan affected his eye.</p> <p>4 BY MR. SLATER:</p> <p>5 Q. Move to strike after "I don't</p> <p>6 dispute that."</p> <p>7 If his condition was caused by</p> <p>8 something other than the olmesartan -- I'm</p> <p>9 talking about his gastrointestinal condition --</p> <p>10 they would not be able to say what they say on</p> <p>11 the bottom right corner of page 2, that last</p> <p>12 paragraph where it says:</p> <p>13 "The case described here</p> <p>14 demonstrated full symptomatic and pathologic</p> <p>15 resolution after suspension of olmesartan within</p> <p>16 a 4-month period."</p> <p>17 You wouldn't expect them to be</p> <p>18 able to say that if this gastrointestinal</p> <p>19 syndrome was due to something other than the</p> <p>20 olmesartan; correct?</p> <p>21 MR. CHRISTIAN: Objection. Form.</p> <p>22 THE WITNESS: I mean, as I said,</p> <p>23 it could be a coincidence, and it's only</p> <p>24 one patient we're talking about here.</p>	<p>1 described, to a reasonable degree of medical</p> <p>2 certainty the likely cause of that</p> <p>3 gastrointestinal syndrome is the olmesartan in</p> <p>4 this patient. That's the likely cause; correct?</p> <p>5 MR. CHRISTIAN: Objection. Form.</p> <p>6 THE WITNESS: Well, I just stated</p> <p>7 that I don't know that I accept the idea</p> <p>8 that the histopathologic resolution was</p> <p>9 complete, which you just stated the</p> <p>10 authors said, but to my look at this</p> <p>11 figure I'm not convinced that it's</p> <p>12 resolved.</p> <p>13 BY MR. SLATER:</p> <p>14 Q. Are you holding yourself out as</p> <p>15 an expert in the field of histopathology and the</p> <p>16 reading of slides?</p> <p>17 A. I think that I -- although I'm</p> <p>18 not a board-certified pathologist, most of my</p> <p>19 papers have histopathology in them, and I consult</p> <p>20 multiple times a week with our two different</p> <p>21 research pathologists that I work with in all my</p> <p>22 projects. So I have a high level of</p> <p>23 understanding of histopathology.</p> <p>24 Q. As between the biopsy images in</p>

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<p>1 Figure 1 versus Figure 2, do you agree that there 2 is significant improvement in the histopathology? 3 A. Yes. 4 Q. So taking together the 5 significant improvement in the histopathology at 6 14 weeks, the resolution of the clinical symptoms 7 of non-bloody diarrhea, vomiting, and a 20-pound 8 weight loss after the patient stopped taking the 9 olmesartan, the likely cause of the 10 gastrointestinal syndrome is olmesartan. 11 That's the likely cause; correct? 12 MR. CHRISTIAN: Objection. Form. 13 THE WITNESS: It is a potential 14 cause, yes. 15 BY MR. SLATER: 16 Q. Likely cause; right? 17 A. Say it again. 18 Q. Likely cause; correct? 19 MR. CHRISTIAN: You have to try 20 one more time, Adam. We didn't hear that 21 one at all. 22 BY MR. SLATER: 23 Q. Okay. That is the likely cause; 24 correct?</p>	<p>1 MR. CHRISTIAN: Objection. Form. 2 THE WITNESS: I think as they 3 laid it out here in this very low-tiered 4 journal and a single patient, I'd be 5 willing to say that with the way they 6 presented the data that this is the most 7 likely cause, but I really can't be 8 sure -- 9 BY MR. SLATER: 10 Q. Thank you. 11 A. -- of other potential factors in 12 this case. 13 MR. SLATER: Move to strike from 14 "but" forward. 15 Let's look at document 10 now, 16 the Greywoode article. 17 THE REPORTER: Exhibit 16. 18 (Document marked for 19 identification purposes as Gutman 20 Exhibit 16.) 21 THE WITNESS: Oh, this is a 22 different Greywoode, is it not? Oh. 23 BY MR. SLATER: 24 Q. Doctor, did you do any power</p>
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<p>1 A. I mean, with the same degree of 2 likeliness that's in some of the other case 3 series. 4 I'm not sure what this article, 5 which is one patient, adds, considering that it's 6 published in a journal that I've never heard of 7 from a somewhat disrupted -- disreputable pub -- 8 Hindawi Press is notorious for -- I think they 9 have something like 1,000 journals, and I'm often 10 asked to be contributing articles to their 11 journals that I'm not sure if they even exist. 12 But I guess this must have existed, but it's not 13 a very reputable place for this to have been 14 published. 15 Q. Move to strike. 16 Taking the information described 17 in this case report, assuming it to be accurate, 18 as you described it, the improvement of the 19 villous architecture, the resolution of the 20 clinical symptoms of diarrhea, vomiting, and a 21 20-pound weight loss, when you put all that 22 together with all the information provided here, 23 the most likely cause for this syndrome is 24 olmesartan; correct?</p>	<p>1 calculation in connection with the number of 2 patients studied in this article? 3 A. No. 4 Q. Of over -- rephrase. 5 Of over 2,000 patients in the 6 endoscopy group, only 22 had been on olmesartan 7 ;correct? 8 This is what it says on page 7 of 9 your report at the top. 10 A. Okay. Okay. 11 Q. Did you evaluate whether 22 12 patients was enough in that group to come to a 13 statistically significant conclusion one way or 14 the other? 15 A. So one of the things that, you 16 know, you can do is, you can look at confidence 17 intervals and, you know, you can get some 18 assessment by the -- by that what the confidence 19 level you should have about the conclusions. 20 And, you know, the P value -- 21 Q. They actually talk about that on 22 page 1243 just above the conclusion; right? 23 A. Yeah, they -- 24 Q. They actually evaluate the data</p>

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<p>1 and say because of the low number of patients 2 taking olmesartan that there may be an 3 association not detectable because of the power; 4 right?</p> <p>5 A. Yeah, I think that's fine. Sure. 6 You can say that.</p> <p>7 Yet, in the beginning of the 8 paragraph, they say:</p> <p>9 "The strength of the study 10 includes the large sample size as well as the 11 comprehensive and protocol direct in-person 12 solicitation of medication use."</p> <p>13 Q. That would be a large sample size 14 of the total number of people studied --</p> <p>15 A. Right.</p> <p>16 Q. -- but when you look at the total 17 number of people on olmesartan, that's a very low 18 number; correct?</p> <p>19 A. I mean, it's low. I don't know 20 if I would say very low.</p> <p>21 Q. 0.7 percent to 1 percent of the 22 study participants, which was a total of 22 23 patients who got endoscopy and 83 out of over 24 12,000 who got colonoscopy.</p>	<p>1 study to try to see this type of association or 2 causal association; correct?</p> <p>3 A. I think it really depends. I 4 cannot give you a generalization because the way 5 all these types of studies were done are very 6 different.</p> <p>7 I mean, as you know, there's 8 multiple studies from the same institution that 9 were all done a completely different way.</p> <p>10 Because you have Greywoode, Lagana. And what's 11 the other one? And DeGaetani.</p> <p>12 So it's like, you know, they 13 were -- they were all done in totally different 14 ways. So I can't generalize between studies if 15 that's what you want me to do.</p> <p>16 Q. Did you read Dr. Lebwohl's 17 deposition transcript?</p> <p>18 A. I skimmed through it a long time 19 ago. I don't remember the exact date.</p> <p>20 Q. It's not on your list.</p> <p>21 A. I don't think I spent more than 22 about five minutes on it. We can add it to the 23 list.</p> <p>24 Q. And you didn't list Dr. Lagana's</p>
<p style="text-align: center;">Page 263</p> <p>1 So it's a total of 105 patients; 2 right?</p> <p>3 A. Uh-huh. Right. But, for 4 example, if you look at the -- the pathology 5 reports section of the results in the abstract, 6 when you look at a P value of .61 for what 7 they're calling histologic diagnosis of celiac 8 disease -- so we all agree that maybe that wasn't 9 the best choice of words, but for histologic 10 diagnosis of villous atrophy and inflammation.</p> <p>11 So a P value of .61 suggests that 12 you're so far away, you would probably need to 13 increase the number of patients. Well, actually, 14 here it's a little confusing the way it's written 15 because they're combining endoscopy and 16 colonoscopy.</p> <p>17 But you would have to increase 18 the number of patients by a massive amount to 19 ever see any association. To the point because 20 the P value is .6. It's so far away from ever 21 being significant.</p> <p>22 Q. And that analysis would apply 23 basically across the board in terms of how many 24 patients you'd need if you were going to run a</p>	<p style="text-align: center;">Page 265</p> <p>1 deposition transcript either, did you?</p> <p>2 A. I don't remember reading his.</p> <p>3 Q. I'm sorry. I didn't hear you.</p> <p>4 What?</p> <p>5 A. I don't remember reading his.</p> <p>6 MR. SLATER: Laura, let's go to 7 document 3. I think it's document 3. It 8 might be 3 or 21. It's a letter. 9 "Olmesartan-induced enterocolitis" in 10 "Pathology."</p> <p>11 MS. PITTLER: Got it. It's 21.</p> <p>12 MR. SLATER: Thanks.</p> <p>13 THE REPORTER: Exhibit 17. 14 (Document marked for 15 identification purposes as Gutman 16 Exhibit 17.)</p> <p>17 BY MR. SLATER:</p> <p>18 Q. Doctor, looking at this, it's a 19 letter written by Gallivan and Brown, and they 20 talk about a 78-year-old woman. They give her 21 clinical history, who had been prescribed 22 olmesartan for four years.</p> <p>23 Do you see that --</p> <p>24 A. Yes.</p>

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<p>1 Q. -- in the left column?</p> <p>2 A. Yes.</p> <p>3 Q. It talks about her other regular</p> <p>4 medications and that there was no history of</p> <p>5 recent use of a nonsteroidal anti-inflammatory</p> <p>6 medication.</p> <p>7 A. Right.</p> <p>8 Q. And that over the past four</p> <p>9 months, she experienced severe watery diarrhea,</p> <p>10 which resulted in three hospital admissions,</p> <p>11 including intensive care unit admission for acute</p> <p>12 renal failure secondary to dehydration.</p> <p>13 Do you see that?</p> <p>14 A. Right.</p> <p>15 Q. Then it says that upper endoscopy</p> <p>16 and colonoscopy were performed and the biopsies</p> <p>17 revealed mild villous blunting in the proximal</p> <p>18 small intestine with intraepithelial</p> <p>19 lymphocytosis and lamina propria inflammation;</p> <p>20 correct?</p> <p>21 A. Yes.</p> <p>22 Q. That's what's related there?</p> <p>23 A. Right.</p> <p>24 Q. They then talk about the</p>	<p>1 complete resolution of the enteropathy-like</p> <p>2 changes.</p> <p>3 That's -- that's what is related</p> <p>4 in terms of the clinical course of that patient;</p> <p>5 correct?</p> <p>6 A. Okay.</p> <p>7 Q. The fact that when they</p> <p>8 discontinued the olmesartan and then put her back</p> <p>9 and it looks like in a controlled way,</p> <p>10 selectively recommencing only the olmesartan, the</p> <p>11 diarrhea returned.</p> <p>12 That's what it says; right?</p> <p>13 MR. CHRISTIAN: Objection. Form.</p> <p>14 THE WITNESS: Well, an important</p> <p>15 point is that they also reinstated oral</p> <p>16 intake. So the bowel rest that she had</p> <p>17 had where she was on TPN was no longer in</p> <p>18 play. So there could have been something</p> <p>19 related to the oral intake like that</p> <p>20 could be leading to the diarrhea as well.</p> <p>21 BY MR. SLATER:</p> <p>22 Q. Okay. It's more likely that when</p> <p>23 they took her off the olmesartan, she got better.</p> <p>24 Then they put her back on it.</p>
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<p>1 colonoscopy and the findings on the colonic</p> <p>2 biopsies.</p> <p>3 And then if you go into the</p> <p>4 second column, they talk about the fact that</p> <p>5 serum tissue transglutaminase antibodies were</p> <p>6 negative, and the clinical setting did not</p> <p>7 support an autoimmune enteropathy or</p> <p>8 immunodeficiency syndrome.</p> <p>9 Do you see what I just read?</p> <p>10 A. Yes.</p> <p>11 Q. Then they say:</p> <p>12 "Withdrawal of olmesartan and</p> <p>13 atorvastatin with implementation of total</p> <p>14 parenteral nutrition and oral budesonide produced</p> <p>15 resolution of diarrhea. On selectively</p> <p>16 recommencing only olmesartan and oral intake, the</p> <p>17 diarrhea returned."</p> <p>18 Do you see that?</p> <p>19 A. Yes.</p> <p>20 Q. "Her anti-hypertensive medication</p> <p>21 was subsequently changed to ramipril and the</p> <p>22 diarrhea again resolved."</p> <p>23 And then they talk about the fact</p> <p>24 that a subsequent colonoscopy was done and showed</p>	<p>1 Even the fact that they let her</p> <p>2 have oral intake again, as between the two, the</p> <p>3 likelier cause of the diarrhea would be the</p> <p>4 olmesartan; correct?</p> <p>5 MR. CHRISTIAN: Objection. Form.</p> <p>6 THE WITNESS: Well, not if she</p> <p>7 had seronegative celiac disease and she</p> <p>8 went on oral intake that had gluten in</p> <p>9 it.</p> <p>10 BY MR. SLATER:</p> <p>11 Q. Let's look at what happened next.</p> <p>12 Then they changed her</p> <p>13 anti-hypertensive to take her off olmesartan</p> <p>14 again and she got better again.</p> <p>15 When you have -- so now we have a</p> <p>16 positive dechallenge, a positive rechallenge, and</p> <p>17 another positive dechallenge.</p> <p>18 When you look at that together,</p> <p>19 for this patient with the information here, the</p> <p>20 most likely cause of her gastrointestinal</p> <p>21 syndrome is the olmesartan; correct?</p> <p>22 MR. CHRISTIAN: Objection. Form.</p> <p>23 THE WITNESS: You know, again,</p> <p>24 it's like the last case. Your -- your</p>

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<p>1 quality of evidence here, this is below a 2 case series. It's just an individual 3 case report.</p> <p>4 So I don't dispute that on face 5 value it looks like this is the most 6 likely cause, but this is one patient, 7 again, published in a journal that I've 8 never heard of.</p> <p>9 BY MR. SLATER:</p> <p>10 Q. Based on the evidence here, the 11 most likely cause is the olmesartan, just taking 12 the evidence presented here; correct?</p> <p>13 MR. CHRISTIAN: Objection. Form.</p>	<p>1 the conclusion of this article written by 2 Marietta, Cartee, Rishi, and Dr. Murray. 3 His conclusion -- his conclusion 4 is: 5 "The drug-associated enteropathy 6 that is most common and serious is that seen with 7 olmesartan albeit at an extremely low rate." 8 You see what I just read?</p> <p>9 A. Yes.</p> <p>10 Q. Okay. Dr. Murray then states: 11 "One should then suspect OAE in 12 any patient who presents with severe diarrhea and 13 weight loss. Many of the features associated 14 with OAE are also found in the enteropathy found 15 in celiac disease. Because of this, one should 16 review any celiac disease diagnosis for any use 17 of olmesartan at the time of diagnosis."</p> <p>18 A. Right.</p> <p>19 Q. Do you see what I just read?</p> <p>20 A. Yep.</p> <p>21 Q. That's a reasonable 22 recommendation to physicians what I just read 23 from Dr. Murray; correct?</p> <p>24 A. I mean, this is an opinion piece.</p>
<p>1 Very simply, and I think you just 2 said it two answers ago.</p> <p>3 Based on the information in this 4 case report, for this patient the most likely 5 cause of the gastrointestinal syndrome is the 6 olmesartan; correct?</p> <p>7 MR. CHRISTIAN: Objection. Form.</p> <p>8 THE WITNESS: With the 9 information that's presented here, but I 10 haven't had the opportunity to review 11 this case record, to the extent that I 12 have been able to with some of the cases 13 in this litigation.</p> <p>14 MR. SLATER: Move to strike from 15 "but" forward.</p> <p>16 Let's look now at document 12. 17 Let's mark that.</p> <p>18 THE REPORTER: Exhibit 18. 19 (Document marked for 20 identification purposes as Gutman 21 Exhibit 18.)</p> <p>22 BY MR. SLATER:</p> <p>23 Q. All right. Doctor, this article, 24 which I believe is on your list, I want to go to</p>	<p>1 So, you know, I don't have a way to put it in any 2 context other than that.</p> <p>3 Q. The question is: Is that a 4 reasonable recommendation to physicians seeing 5 patients with this type of a clinical 6 presentation? Do you agree that's a reasonable 7 recommendation?</p> <p>8 A. I think that in medicine we 9 always like to be conservative, and if we think 10 that anything has been published, we always 11 factor that into our consideration.</p> <p>12 Q. If a patient comes into a 13 gastroenterologist or a family physician, whoever 14 it may be, who takes olmesartan and the patient 15 has severe diarrhea, dehydration, and weight 16 loss, based upon the medical literature as it 17 stands now, it's a reasonable -- reasonable 18 decision to take the patient off the olmesartan 19 and see if the patient gets better, and if the 20 patient does, to just switch their 21 anti-hypertensive and avoid having to do invasive 22 biopsies and that sort of thing.</p> <p>23 That's a reasonable approach; 24 correct?</p>

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<p>1 MR. CHRISTIAN: Objection. Form.</p> <p>2 THE WITNESS: So I think the</p> <p>3 reasonable approach if somebody is that</p> <p>4 sick is to stop any medication that you</p> <p>5 can find that's ever been associated with</p> <p>6 a GI distress, and then make a decision</p> <p>7 about for each of those medications</p> <p>8 whether they're needed or not or whether</p> <p>9 an alternative can be used. So there's</p> <p>10 many medications that can cause GI side</p> <p>11 effects.</p> <p>12 BY MR. SLATER:</p> <p>13 Q. Let's -- let's talk about a</p> <p>14 patient who is on olmesartan and is not taking</p> <p>15 any other medications that cause severe diarrhea,</p> <p>16 dehydration, and weight loss, that that's --</p> <p>17 olmesartan is the only drug they're taking that</p> <p>18 is known to cause that spectrum.</p> <p>19 Based on the literature that</p> <p>20 exists now, if a patient came into a doctor</p> <p>21 reporting those symptoms, it would be reasonable</p> <p>22 for the doctor to stop the olmesartan and then,</p> <p>23 if the person were to improve and then get</p> <p>24 better, to not restart the olmesartan but to go</p>	<p>1 looked at that criteria based on the GRADE</p> <p>2 approach, Grading of Recommendations, Assessment,</p> <p>3 Development, and Evaluation approach?</p> <p>4 A. Right.</p> <p>5 Q. That approach, the GRADE</p> <p>6 approach, is that something you brought to this,</p> <p>7 or is that something that the attorneys asked you</p> <p>8 to use?</p> <p>9 A. So I was asked to be sure to</p> <p>10 address the Bradford Hill criteria, and then I</p> <p>11 spent time on my own trying to find good articles</p> <p>12 that carefully described that nomenclature, and I</p> <p>13 found the two that I cited here. And I felt that</p> <p>14 the -- I saw multiple references to this GRADE</p> <p>15 approach and so I -- I tried to find what looked</p> <p>16 like an earlier original use of it, and that's</p> <p>17 how I found the article. So it was all something</p> <p>18 that I found.</p> <p>19 Q. The GRADE approach, you had not</p> <p>20 applied that or used that previously; correct?</p> <p>21 A. Correct.</p> <p>22 Q. Did you actually apply the GRADE</p> <p>23 approach in terms of how you calculate the value</p> <p>24 of different criteria, or did you just generally,</p>
<p>1 to another high pressure -- high blood pressure</p> <p>2 medication; correct?</p> <p>3 MR. CHRISTIAN: Objection. Form.</p> <p>4 THE WITNESS: I think that's</p> <p>5 reasonable, but I don't think that most</p> <p>6 doctors are aware of this syndrome.</p> <p>7 MR. SLATER: Let's take a break</p> <p>8 for about five or 10 minutes. I'm pretty</p> <p>9 close to being done, if not done. Let me</p> <p>10 just check my notes, all right, Randy?</p> <p>11 And then I think I might be done.</p> <p>12 MR. CHRISTIAN: All right.</p> <p>13 Thanks, Adam.</p> <p>14 THE VIDEOGRAPHER: Time is 3:27.</p> <p>15 We're going off the record.</p> <p>16 MR. SLATER: Let's go off the</p> <p>17 video.</p> <p>18 (A brief recess was taken.)</p> <p>19 THE VIDEOGRAPHER: The time now</p> <p>20 is 3:42. We are back on the record.</p> <p>21 BY MR. SLATER:</p> <p>22 Q. Doctor, in looking at your</p> <p>23 report, you mentioned the Bradford Hill criteria,</p> <p>24 which we talked about earlier, and that you</p>	<p>1 you know, consider it as you applied the Bradford</p> <p>2 Hill criteria?</p> <p>3 A. I think I just generally</p> <p>4 considered it.</p> <p>5 Q. Now, I just want to come back to</p> <p>6 one thing, and this is really the most important</p> <p>7 question of the day.</p> <p>8 We talked about the Basson</p> <p>9 studies and some questions you had about the</p> <p>10 French data.</p> <p>11 I just want to know: Is that</p> <p>12 because of your concern that the French have</p> <p>13 outrageous accents?</p> <p>14 A. (Laugh). I told you. I've got</p> <p>15 two in my lab now and I had two other post-docs.</p> <p>16 So I've had four French people work with me. So</p> <p>17 that's not the problem.</p> <p>18 Q. Okay. I just want to make sure</p> <p>19 that there's not a Monty Python issue here.</p> <p>20 A. No.</p> <p>21 Q. That's -- I want to reserve the</p> <p>22 rest of my time for requestioning if defense</p> <p>23 counsel questions Dr. Wilson. Thank you.</p> <p>24 THE VIDEOGRAPHER: Randy, before</p>

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<p>1 we go, am I supposed to tape?</p> <p>2 MR. CHRISTIAN: I just have a few</p> <p>3 questions, Adam. I'm fine with not</p> <p>4 switching the camera, but whatever you --</p> <p>5 if you're fine with it, we can just do my</p> <p>6 questions without.</p> <p>7 MR. SLATER: Whatever you want to</p> <p>8 do.</p> <p>9 MR. CHRISTIAN: Yeah, let's</p> <p>10 just -- I don't look as good as Adam. So</p> <p>11 I'll stay off the camera.</p> <p>12 MR. SLATER: (Laugh). Thank you.</p> <p>13 I'm really feeling flattered. (Laugh).</p> <p>14 MR. CHRISTIAN: All right. Are</p> <p>15 you ready, Adam? We're still on the</p> <p>16 record?</p> <p>17 THE VIDEOGRAPHER: Yes.</p> <p>18 MR. CHRISTIAN: Okay.</p> <p>19 EXAMINATION</p> <p>20 BY MR. CHRISTIAN:</p> <p>21 Q. Dr. Wilson, my name is Randy</p> <p>22 Christian. I represent the defendants in this</p> <p>23 case.</p> <p>24 Do you understand that?</p>	<p>1 The number one criteria you list</p> <p>2 there is strength of association; correct?</p> <p>3 A. Correct.</p> <p>4 Q. In your evaluation of general</p> <p>5 causation in this case, did you evaluate the</p> <p>6 strength of the association that you found in the</p> <p>7 published medical literature?</p> <p>8 A. Yes.</p> <p>9 Q. Is that something that you do</p> <p>10 every day in your practice and in your research</p> <p>11 is evaluate strength of association?</p> <p>12 A. Yes, I --</p> <p>13 MR. SLATER: Objection.</p> <p>14 BY MR. CHRISTIAN:</p> <p>15 Q. You can still answer.</p> <p>16 A. Yes, I do that. Whenever I'm</p> <p>17 considering any type of data that's published,</p> <p>18 whether it be something that's already published</p> <p>19 or something that I'm handling as an editor for a</p> <p>20 journal or whether I'm handling as a reviewer for</p> <p>21 an article, I need to determine what I think the</p> <p>22 quality of the associations are within that work.</p> <p>23 Q. And you use -- utilize that</p> <p>24 methodology in your evaluation in Exhibit No. 4,</p>
<p>1 A. Yes.</p> <p>2 Q. Okay. I'm handing you what's</p> <p>3 been marked as Exhibit 9 to your deposition,</p> <p>4 which you indicated was your updated CV or</p> <p>5 resume, as of what date?</p> <p>6 A. February 20, 2017.</p> <p>7 Q. Okay. And is Exhibit 9, is that</p> <p>8 a true and correct copy of your CV?</p> <p>9 A. Yes.</p> <p>10 Q. Does it accurately summarize your</p> <p>11 education, training, and professional experience?</p> <p>12 A. Yes.</p> <p>13 Q. Will you turn to your report,</p> <p>14 which is Exhibit No. 4 in this case.</p> <p>15 Do you have your report in front</p> <p>16 of you?</p> <p>17 A. Yes.</p> <p>18 Q. Turn to page 10. At the bottom</p> <p>19 of page 10, you were just asked a few questions</p> <p>20 about -- this is where the section starts on the</p> <p>21 Bradford Hill criteria; is that correct?</p> <p>22 A. Yes.</p> <p>23 Q. Okay. I want to ask you some</p> <p>24 questions about this criteria.</p>	<p>1 your report?</p> <p>2 A. Yes.</p> <p>3 MR. SLATER: Objection.</p> <p>4 BY MR. CHRISTIAN:</p> <p>5 Q. Or did you use that methodology</p> <p>6 in your report?</p> <p>7 A. Yes.</p> <p>8 Q. What is the second criteria</p> <p>9 listed on the top of page 11?</p> <p>10 A. It should be consistency.</p> <p>11 Q. Okay. And did you evaluate</p> <p>12 consistency in looking at the evidence in this</p> <p>13 case as it relates to olmesartan and sprue-like</p> <p>14 enteropathy?</p> <p>15 A. Yes. In fact, that's really a</p> <p>16 striking flaw in the literature is that there is</p> <p>17 so much inconsistency in trying to define this</p> <p>18 syndrome, and I've discussed some of this in my</p> <p>19 deposition today.</p> <p>20 Q. And in looking at the issue of</p> <p>21 consistency, is that something that you do every</p> <p>22 day in your practice and research?</p> <p>23 A. Yes.</p> <p>24 Q. The next item there listed is</p>

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<p>1 temporality or study design suitability; is that 2 correct?</p> <p>3 A. Yes.</p> <p>4 Q. And did you use the methodology 5 of analyzing temporality or study design 6 suitability in coming up with your opinions in 7 this case?</p> <p>8 A. Yes.</p> <p>9 Q. Is that something you do every 10 day in your practice and research?</p> <p>11 A. Yes. We often have --</p> <p>12 MR. SLATER: Objection.</p> <p>13 THE WITNESS: Can I continue?</p> <p>14 BY MR. CHRISTIAN:</p> <p>15 Q. Yes.</p> <p>16 A. So often in designing our human 17 studies -- for example, I'm mentoring a senior 18 fellow, who's joining our faculty in a new study 19 that we're starting, and we had to very carefully 20 think through the study design of the 21 measurements we were going to make in patients on 22 and off the medication for Crohn's disease. And 23 we do the same thing when we design animal 24 experiments.</p>	<p>1 A. Yes. In fact, I indicated that 2 there's no evidence of a biological gradient in 3 these studies.</p> <p>4 Q. And is evaluating biological 5 gradient something you do every day in your 6 practice and research?</p> <p>7 A. Yes. When we design experiments, 8 we often will do a dose-response of an inhibitor. 9 We will use dose-responses of a stimulant that 10 we're using, such as the amount of bacteria we 11 add to cells. So we're always factoring that 12 type of thing in.</p> <p>13 Q. And with respect to the next 14 category listed, specificity, do you evaluate the 15 issue of specificity as a methodology in your 16 everyday practice?</p> <p>17 A. Yes, it is.</p> <p>18 MR. SLATER: Objection.</p> <p>19 THE WITNESS: So there's this 20 concept of whenever you're evaluating any 21 clinical studies, you should factor in 22 sensitivity and specificity, but in the, 23 you know, that's sort of assessing, for 24 example, the merits of a certain test.</p>
<p>1 Q. And the next item listed there is 2 biological gradient.</p> <p>3 Can you explain what that means?</p> <p>4 A. So it's very important to 5 consider the idea that if something just is 6 cytotoxic at a low dose and you can't establish 7 if there's a gradient, it's very hard to 8 determine the effect in an experimental system.</p> <p>9 In the human system, it's 10 implicit that if somebody -- if patients were to 11 have a deleterious effect of a medication, it 12 seems that there should be some evidence of a 13 dose effect; i.e. that, for example, some 14 medications might be well tolerated at one dose, 15 but if you increase it high enough, it could 16 lower the seizure threshold and they could get 17 seizures, or it could cause acute renal failure 18 or what have you.</p> <p>19 So that oftentimes it's very 20 important to be able to determine if there is a 21 gradient to an adverse effect.</p> <p>22 Q. And, Dr. Wilson, did you analyze 23 biological gradient in your analysis as 24 summarized in Exhibit No. 4?</p>	<p>1 Here what we're looking at in 2 specificity, it's something different. 3 We're trying to see, to determine if 4 there were to be causation, there needs 5 to be a very specific outcome from a 6 specific exposure.</p> <p>7 So this idea that there could be 8 a loose collection of responses is 9 something that, in my opinion, lowers the 10 quality of the evidence.</p> <p>11 BY MR. CHRISTIAN:</p> <p>12 Q. Did you utilize this methodology 13 in coming up with your opinions in Exhibit No. 4?</p> <p>14 A. I did.</p> <p>15 Q. The next one is called biological 16 plausibility.</p> <p>17 What is that?</p> <p>18 A. Well, I think that's the biggest 19 sticking point in this entire case, which is that 20 in order -- it's my understanding that, according 21 to Bradford Hill criteria, in order for something 22 to be likely to be causal, there should be a 23 plausible biological mechanism.</p> <p>24 And in this scenario, I gave the</p>

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<p>1 example of how things like the immunosuppressive 2 effects of HIV can be quantified by looking at a 3 CD4 count, for example, and that can be 4 predictive of whether people get an 5 immunocompromised state that leads to 6 opportunistic infection.</p> <p>7 Here we don't have any evidence 8 of any particular driving force because it was 9 originally speculated that it would be TGF beta 10 driven, a loss of TGF beta immunoregulation, but 11 that was really an overly simplistic thought 12 process and there are many immunoregulatory 13 pathways and, in fact, when they looked in the 14 Marietta paper at TGF beta, signaling they 15 couldn't see any differences.</p> <p>16 Q. Dr. Wilson, was part of your 17 methodology in coming up with your opinions in 18 Exhibit 4 analyzing biologic plausibility?</p> <p>19 A. It was.</p> <p>20 Q. And is that something you do in 21 your everyday practice and research?</p> <p>22 A. Absolutely.</p> <p>23 Q. Number 7 is coherence. 24 Did you analyze coherence in</p>	<p>1 A. I tried to see if there was any, 2 and I didn't find much evidence of that. 3 Q. Is that something that you do in 4 your everyday practice and research?</p> <p>5 A. Yes.</p> <p>6 Q. Number 8 is experimental 7 evidence. 8 Did you use in your methodology 9 an analysis of experimental evidence relating to 10 sprue-like enteropathy and olmesartan?</p> <p>11 A. I tried, but I couldn't find 12 much. The Marietta paper, I already discussed in 13 my report that the deficiencies there in terms of 14 trying to provide evidence of a mechanism, and 15 also animal data is weak. So the experimental 16 evidence is something I considered, but it's 17 poor.</p> <p>18 Q. Do you, Dr. Wilson, analyze 19 experimental evidence in your everyday practice 20 and research?</p> <p>21 A. I do that a lot. That's what I 22 do every day.</p> <p>23 Q. Okay. And number 9, reasoning by 24 analogy.</p>
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<p>1 looking at the medical literature that you 2 summarize in Exhibit No. 4?</p> <p>3 A. So I found this one to be tough 4 because that's supposed to be looking at the 5 natural history of a disease, and since this is a 6 syndrome that seems to occur in a very small 7 number of cases, I found it very difficult to put 8 together a coherent explanation of what this 9 disease process is. So, for example, as I 10 enumerated here, because of the poor quality of 11 the evidence.</p> <p>12 Does it include things like 13 gastric and colonic involvement? Is that 14 necessary to say that somebody has the syndrome?</p> <p>15 What is the role of the HLA status? What is the 16 role of various other factors that were put forth 17 but don't seem to be consistent between the 18 studies?</p> <p>19 So that further evidenced that 20 causation is less likely because there's not 21 coherence between the studies.</p> <p>22 Q. As part of your methodology in 23 coming up with your opinions in this case, did 24 you utilize the concept of coherence?</p>	<p>1 Did you evaluate reasoning by 2 analogy as part of your methodology in coming up 3 with your opinions in this case?</p> <p>4 MR. SLATER: Objection.</p> <p>5 THE WITNESS: Yes, I did because 6 I considered whether or not other ARBs 7 could have the same effect, and the 8 evidence on that is the jury is still 9 out, so to speak, because there's a 10 couple of scattered case reports, but 11 there hasn't been any real effort to try 12 and show that it's a class-specific 13 effect. So there's not really any 14 reasoning by analogy.</p> <p>15 BY MR. CHRISTIAN:</p> <p>16 Q. So in your everyday practice at 17 Vanderbilt University and your work at the VA 18 hospital, do you incorporate these nine different 19 methodologies when you're trying to determine 20 whether something is causing something else?</p> <p>21 A. I do.</p> <p>22 MR. SLATER: Objection.</p> <p>23 MR. CHRISTIAN: Thank you, 24 Dr. Wilson. That's all the questions I</p>

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<p>1 have.</p> <p>2 MR. SLATER: I have a few</p> <p>3 follow-up questions.</p> <p>4 FURTHER EXAMINATION</p> <p>5 BY MR. SLATER:</p> <p>6 Q. Start at the end and might just</p> <p>7 to be clear, you don't believe that any other</p> <p>8 ARBs cause sprue-like enteropathy or a similar</p> <p>9 syndrome? You don't believe that there's</p> <p>10 adequate evidence to make that statement.</p> <p>11 Do I understand you correctly?</p> <p>12 A. I didn't say that there's no</p> <p>13 evidence whatsoever. There's a few scattered</p> <p>14 case reports, and so I don't know whether anybody</p> <p>15 has really done anything more other than the</p> <p>16 articles I reviewed.</p> <p>17 So, for example, in the Lagana</p> <p>18 study, they also looked at other ARBs, other</p> <p>19 ARBs, and didn't seem to find much of an</p> <p>20 association, but I don't know what other</p> <p>21 literature might come out in the next couple</p> <p>22 years.</p> <p>23 Q. Do you have an opinion right now</p> <p>24 to a reasonable degree of medical certainty as to</p>	<p>1 that you can manipulate them in culture to more</p> <p>2 closely mimic either colon or small intestinal</p> <p>3 cells. But they're not really a very good model</p> <p>4 of small intestinal cells because they're colon</p> <p>5 cancer cells.</p> <p>6 Q. It is accepted in the scientific</p> <p>7 world that you can use CACO 2 cells to evaluate</p> <p>8 small intestinal disease processes; correct?</p> <p>9 A. I think that's controversial. I</p> <p>10 don't think it's accepted.</p> <p>11 Q. Studies in the peer-reviewed</p> <p>12 literature where CACO 2 cells were used, for</p> <p>13 example, to evaluate issues with celiac disease;</p> <p>14 correct?</p> <p>15 A. There may be, but, again, it's</p> <p>16 just a cell culture model. You know, it's just</p> <p>17 one piece. It's just one model system.</p> <p>18 Q. The fact that they used CACO 2</p> <p>19 cells in the Marietta study, that's not a reason</p> <p>20 in and of itself to discount or invalidate those</p> <p>21 findings; correct?</p> <p>22 A. I mean, if they had done the</p> <p>23 studies in a better manner where I would find the</p> <p>24 data more interpretable, you know, if it were to</p>
<p>1 whether other ARBs cause a similar syndrome to</p> <p>2 sprue-like enteropathy or olmesartan-associated</p> <p>3 enteropathy?</p> <p>4 A. I think from the few case</p> <p>5 reports, I wouldn't use the word "cause." I</p> <p>6 would say it is possible that there could be an</p> <p>7 association with some of the other ARBs, but</p> <p>8 right now the -- the clicker in terms of counting</p> <p>9 the number of cases is -- is still low.</p> <p>10 Q. In your analysis of the Marietta</p> <p>11 article, which you were just asked about, you</p> <p>12 talked about CACO 2 cells. Remember you talked</p> <p>13 about a little of that in your report a little?</p> <p>14 A. Yes. Yes.</p> <p>15 Q. Yes?</p> <p>16 A. Yes.</p> <p>17 Q. And it's inappropriate to use</p> <p>18 CACO 2 cells in evaluating small intestinal</p> <p>19 mechanisms.</p> <p>20 You're not saying that, are you?</p> <p>21 A. So CACO 2s are a hotly debated</p> <p>22 cell model. So there are -- there are -- they</p> <p>23 are a poorly differentiated colon cancer cell</p> <p>24 line, and some that work with them have argued</p>	<p>1 go into a better journal like "Gastroenterology,"</p> <p>2 we would require that they provide evidence in a</p> <p>3 nontransformed system, such as a small intestinal</p> <p>4 aneroid, which are primary cell cultures, either</p> <p>5 2- or 3-dimensional cultures.</p> <p>6 Q. Okay. Move to strike.</p> <p>7 The question I'm asking is very</p> <p>8 simple.</p> <p>9 In your opinion, are you relying</p> <p>10 on the use of CACO 2 cells by the group in the</p> <p>11 Marietta study as a reason to reject their</p> <p>12 findings?</p> <p>13 A. It's one of the reasons. It's</p> <p>14 not a -- it's not the only reason.</p> <p>15 Q. Do you acknowledge that people</p> <p>16 studying celiac disease use CACO 2 cell cultures</p> <p>17 to experiment and study issues with celiac</p> <p>18 disease?</p> <p>19 A. I would have to review that. I'm</p> <p>20 not certain about that, about how commonly that's</p> <p>21 done.</p> <p>22 Q. Would you agree with me that the</p> <p>23 mechanisms described in the Marietta article</p> <p>24 could possibly be related to the mechanism</p>

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1 whereby olmesartan causes this syndrome that's 2 been identified with olmesartan?	1 approach, which you refer to in your report?
3 MR. CHRISTIAN: Objection.	2 A. No.
4 BY MR. SLATER:	3 Q. In any paper or anytime you've 4 spoken to students, have you ever referred to the 5 Oxford Centre for Evidence-Based Medicine 6 standards that you refer to in your report?
5 Q. Do you agree that it's possible 6 that regardless of the flaws that you identify in 7 the study that the conclusion as to the mechanism 8 is accurate?	7 A. No.
9 MR. CHRISTIAN: Objection. Form.	8 MR. SLATER: I have no other 9 questions, unless counsel comes back 10 again. Then we'll play tennis.
10 THE WITNESS: I don't think that 11 anything that they published in that 12 article is valid.	11 MR. CHRISTIAN: No questions. 12 Thanks a lot.
13 BY MR. SLATER:	13 THE VIDEOGRAPHER: Time now is 14 4:03. This deposition has concluded.
14 Q. Well, my question is this. You 15 challenge many things about how the study was 16 done and reported, but my question is this. 17 It's possible that the conclusion 18 is correct despite those flaws that you identify; 19 correct?	15 16 (Deposition concluded at 4:03 p.m.)
20 MR. CHRISTIAN: Objection. Form.	17 * * *
21 THE WITNESS: So the only thing 22 that made it into the conclusion was 23 something vague about immunopathogenesis, 24 which is not -- doesn't say anything, and	18 19 20 21 22 23 24
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1 they relied on this idea of the IL-15 2 overexpression, but the data that was 3 presented for that I did not consider to 4 be valid.	1 - - - - - 2 E R R A T A 3
5 I have a color version of that 6 article. I don't know where it went.	4 PAGE LINE CHANGE
7 BY MR. SLATER:	5 6 REASON: _____
8 Q. Have you ever cited the Bradford 9 Hill criteria in any paper you've ever published?	7 8 REASON: _____
10 A. No.	9 10 REASON: _____
11 Q. Have you ever taught students the 12 use of the Bradford Hill criteria?	11 12 REASON: _____
13 A. So I have not called it that, but 14 in reviewing that for preparation of this, I 15 realized that many of the principles, I have 16 absolutely taught students and residents, 17 post-docs, and junior faculty.	13 14 REASON: _____
18 Q. Okay. Move to strike.	15 16 REASON: _____
19 Have you ever in teaching 20 students referred to the Bradford Hill criteria 21 per se?	17 18 REASON: _____
22 A. No.	19 20 REASON: _____
23 Q. In writing any papers or 24 teaching, have you ever referred to the GRADE	21 22 REASON: _____
	23 24 REASON: _____

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1 2 ACKNOWLEDGMENT OF DEONENT 3 4 I, _____, do 5 hereby certify that I have read the 6 foregoing pages, and that the same is 7 a correct transcription of the answers 8 given by me to the questions therein 9 propounded, except for the corrections or 10 changes in form or substance, if any, 11 noted in the attached Errata Sheet. 12 13 14 15 KEITH T. WILSON, M.D. DATE 16 17 18 Subscribed and sworn to before me this 19 ____ day of _____, 20____. 20 My commission expires: _____ 21 22 _____ 23 24	Page 298
1 CERTIFICATE OF REPORTER 2 DISTRICT OF COLUMBIA) 3 I, DENISE D. VICKERY, CRR/RMR and Notary 4 Public, hereby certify the witness was by me 5 first duly sworn to testify to the truth; that 6 the foregoing deposition was taken at the time 7 and place stated herein; and that the said 8 deposition was recorded stenographically by me 9 and thereafter reduced to printing under my 10 direction; that said deposition is a true 11 record of the testimony given by said witness. 12 13 I certify the inspection, reading and 14 signing of said deposition were NOT waived by 15 counsel for the respective parties and by the 16 witness; and that I am not a relative or 17 employee of any of the parties, or a relative 18 or employee of either counsel, and I am in no 19 way interested directly or indirectly in this 20 action. 21 22 23 Denise D. Vickery, CRR/RMR 24 My Commission expires February 14, 2018	Page 299

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